

REMARKS

Entry of the foregoing, re-examination and reconsideration of the application identified in caption, as amended, pursuant to and consistent with 37 C.F.R. §1.116 and in light of the remarks which follow are respectfully requested.

Respectfully, entry of the amendments will place the application in immediate condition for allowance for the reasons that follow. Accordingly, entry of the amendment is proper.

As correctly indicated in the Office Action summary, Claims 1-57 were pending. The Office Action Summary further indicates that Claims 1-57 stand rejected. By this amendment, Claim 1 is amended, Claims 16-57 are canceled without prejudice or disclaimer, and Claims 58-78 have been added. Thus, Claims 1-15 and 58-78 are currently pending in this application with the entry of this Amendment.

Applicants note with appreciation that the Examiner has indicated that Claims 1-15 would be allowable upon the correction of the underlining in Claim 1. Respectfully, such correction has been made by the present amendment, whereby the deletion of $-(CH_7)_9CH_3$ and the insertion of $-(CH_2)_9CH_3$ therefor (in the definition of R^2) has now been correctly indicated by appropriate underlining and brackets.

Claim 1 has been further amended throughout. Support for the insertion that Y^2 can be H in claim 1 is supported at least by the specification at column 3, line 53. The insertion in claim 1 that Z^2 can be OH is supported at least by column 3, lines 52-53. Support for the definition of X^1 is found at least at column 3, lines 13-16.

New claims 58 and 59 are supported by column 15, lines 4-6. New claim 60 is supported by column 14, line 62. New claim 61 is supported by column 13, line 64 to column 14, line 26. New claim 62 is supported by column 3, lines 57-62, column 4, lines 33-34 and column 6, line 24. New claims 63-66 are supported by column 2, lines 61-63. New claim 67 is supported by column 3, line 53. New claims 68-70 are supported by column 14, lines 10-14 and column 15, lines 28-30. New claim 71 is supported by column 13, lines 61-63 and column 14, lines 15-17. New claims 72 and 73 are supported by column 13, line 64 to column 14, line 18. New claims 74-77 are supported by column 14, line 27-33. New claim 78 is supported by column 16, line 26.

These amendments have been made in accordance with 37 C.F.R. §1.121 as amended on November 7, 2000. As required, attached hereto is an appendix illustrating the amendments made above. Entry of the above amendments is earnestly requested.

The above amendments have been presented solely for the purpose of expediting what appears to be allowable subject matter. Applicants reserve the right to file a continuing application directed to the originally presented claims.

The Declaration was objected to as being insufficient because the Examiner asserted that no error was pointed out specifically. While not necessarily agreeing with this objection, Applicants respectfully request that this objection be held in abeyance until the indication of otherwise allowable subject matter. Applicants express their willingness to consider filing a new Declaration, upon indication that the claims are otherwise allowable.

I. THE REJECTION OF CLAIMS 16-57 AS AN IMPROPER RECAPTURE OF SUBJECT MATTER

Claims 16-57 were rejected as being an improper recapture of subject matter claimed in the application issued as the parent patent, U.S. Patent No. 5,631,394 (hereinafter referred to as "the parent patent").

According to the case law (*Hester Industries v. Stein*, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement*, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp. v. United States*, 221 USPQ 289 (Fed. Cir. 1984)), the recapture rule bars the allowance of a reissue claim that is broader than an original claim surrendered during prosecution of the patented application in an effort to overcome a prior art rejection. See *Hester Industries*, 45 USPQ2d at 1648; *In re Clement*, 45 USPQ2d at 1164.

The instant reissue application is for the reissue of U.S. Patent 5,681,589 (the '589 Patent) issued from Application No. 08/545,164 (Application '164). In the instant reissue application, Claims 16-30 are drawn to a compound, Claims 31, 33 and 49 are drawn to a composition comprising the liposome or compound, and Claims 50-57 are drawn to methods of using the composition. As was discussed in detail in the Amendment and Reply filed on August 20, 2001, the recapture rule should not apply unless the reissue claim is broader than an original claim surrendered during prosecution of the patented application in an effort to overcome a prior art rejection.

Respectfully, while not agreeing with this rejection at least for reasons of record, Applicants submit that this rejection has been obviated by the cancellation of Claims 15-67. Accordingly, withdrawal of this rejection is respectfully requested.

II. THE REJECTION OF CLAIMS 16-57 AS AN IMPROPER BROADENING

Claims 16-57 were also rejected as broadening the reissue claims prohibited by the two-year rule.

The Office Action states that a broadening aspect is present in the reissue application which was not present in the application for patent and the broadening aspect in the reissue application relates to subject matter that applicant previously patented prior to the prosecution of the application. However, as was discussed in detail in the Amendment and Reply filed on August 20, 2001, Applicants filed the instant reissue application seeking the reissue of the '589 Patent within two years of the issue date of the '589 Patent. In other words, claims 16-30 were on file within 2 years of the issue date of the '589 Patent. Thus, applicants submit that claims 16-32 meet the requirements of 35 U.S.C. §251 which permits a reissue patent to be granted enlarging the scope of the claims of the original patent as long as the claims with the enlarged scope are filed within two years from the grant of the original patent. See *In re Graff*, 42 USPQ2d 1471 (Fed. Cir. 1997); *In re Doll*, 164 USPQ 218 (CCPA 1970).

Respectfully, while not agreeing with this rejection for reasons of record, Applicants submit that this rejection has been obviated by the cancellation of Claims 15-67. Accordingly, withdrawal of this rejection is respectfully requested.

III. THE REJECTION OF CLAIMS 52-57 AS AN IMPROPER BROADENING

The Examiner also rejected Claims 52-57, on the ground that the recitation of the specific cancers in these method claims represented an improper broadening of the method

claim for the treatment of cancer in general in the instant patent. Applicants traverse this rejection.

The Official Action states that the Claims reciting specific cancers appear to be unsupported in the specification and that such claims were not previously presented. The Office Action then states that the Claims constitute an improper broadening.

The rejection is improper because the recitation of the specific cancers to be treated actually represented a narrowing, not broadening, of the patented method claim for the treatment of cancer. Column 15, lines 4-6, of the instant patent provides support for the specific cancers recited in Claims 52-57.

Respectfully, while not agreeing with this rejection, Applicants submit that this rejection has been obviated by the cancellation of Claims 52-57. Accordingly, withdrawal of this rejection is respectfully requested.

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is earnestly solicited.

If there are any questions concerning this paper or the application in general, the Examiner is invited to telephone the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: _____

Teresa Stanek Rea
Registration No. 30,427

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

Date: June 12, 2002

Attachment to Amendment dated June 12, 2002

1. (Amended Thrice) A liposome having a bilayer comprising a lipid component which comprises a compound having the formula

$R^1-Y^1-CHZ^1-CH(NY^2Y^3)-CH_2-Z^2$, wherein:

R^1 is a straight-chained alkyl, alkenyl or alkynyl group having from 5 to 19 carbon atoms in the aliphatic chain;

Y^1 is $-CH=CH-$, $-C\equiv C-$ or $-CH(OH)CH(OH)-$;

[each of] Z^1 [and Z^2] is [independently] OH or a conversion-inhibiting group;

Y^2 is H, a phenyl group, an alkyl-substituted phenyl group having from 1 to about 6 [carbons] carbon atoms in the alkyl chain, or an alkyl chain having from 1 to 6 [carbons] carbon atoms;

Y^3 is H or a group having the formula $-C(O)R^2$ or $-S(O)_2R^2$;

R^2 is a straight-chained alkyl moiety selected from the group consisting of $-(CH_2)_3CH_3$, $-(CH_2)_5CH_3$, $-(CH_2)_7CH_3$ and $[-(CH_2)_9CH_3]$ ~~$-(CH_2)_9CH_3$~~ , or an alkenyl group or alkynyl group having from 2 [1] to 23 carbon atoms in the aliphatic chain;

Z^2 is OH or a phosphorylcholine attachment-inhibiting group selected from the group consisting of $-X^1$, $-OX^1$, $-X^2X^3$ and $-OX^2X^3$;

X^1 is selected from the group consisting of $-C(O)H$, $-CO_2H$, $[CH_3(C(CH_3)_3)_2]$ CH_3 , $C(CH_3)_3$, $Si(CH_3)_3$, $SiCH_3(C(CH_3)_3)_2$, $Si(C(CH_3)_3)_3$, $Si(PO_4)_2C(CH_3)_3$, a phenyl group, an alkyl-substituted phenyl group having from 1 to 6 [carbons] carbon atoms in the alkyl chain, an alkyl chain having from 1 to 6 [carbons] carbon atoms, an amino group, a fluorine atom, a chlorine atom, and a group having the formula $C(R^3R^4)OH$;

Attachment to Amendment dated June 12, 2002

X² is selected from the group consisting of CH₂-, C(CH₃)₂-, Si(PO₄)₂-, Si(CH₃)₂-, SiCH₃PO₄-, C(O)- and S(O)₂-;

221
cancel X³ is selected from the group consisting of -C(O)H, -CO₂H, -CH₃, -C(CH₃)₃, -Si(CH₃)₃, -SiCH₃(C(CH₃)₃)₂, -Si(C(CH₃)₃)₃, -Si(PO₄)₂C(CH₃)₃, a phenyl group, an alkyl-substituted phenyl group having from 1 to 6 [carbons] carbon atoms in the alkyl chain, an alkyl chain having from 1 to 6 [carbons] carbon atoms, an amino moiety, a chlorine atom, a fluorine atom, or a group having the formula C(R³R⁴)OH, wherein each of R³ and R⁴ is independently an alkyl chain having from 1 to 6 [carbons] carbon atoms, a phenyl group or an alkyl-substituted phenyl group having from 1 to 6 [carbons] carbon atoms in the alkyl chain;

wherein when Z² is an amino group, R² is an aliphatic chain having from 1 to 9 or from 19 to 23 carbon atoms in the aliphatic chain; *2*

and wherein the compound comprises at least about 5 mole percent of the lipid component.
